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EXAMINER	
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ART UNIT	PAPER NUMBER
1619	

NOTIFICATION DATE	DELIVERY MODE
10/14/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)
	10/559,373	SUMIYOSHI ET AL.
	Examiner	**Art Unit**
	TIGABU KASSA	1619

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 July 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *5* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *07/21/11*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/CHERIE M WOODWARD/
Primary Examiner, Art Unit 1647

Continuation of 11: Applicant's remarks/arguments do not place the case in condition for allowance or in better condition for appeal.

Claims 24 and 30 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Segers et al., (US Patent 5383324, published on January 24, 1995), Veech (US Patent No. 4663166, published on May 5, 1987), Nakamura et al., (US Patent 6867193, published on March 15, 2005), Panter-Brick (Europ. J. Intensive Care Medicine 2, 45-51, 1976), and Kido et al., (US Patent No. 6129925, published on October 10, 2000), for the reasons of record and the reasons set forth herein.

a) Segers:
Applicant argues that Segers neither discloses nor suggests limitation (i) a first solution containing dipotassium hydrogen phosphate(emphasis added), glucose, sodium chloride, sodium lactate, calcium gluconate, magnesium sulfate and zinc sulfate in a first chamber as recited in claim 24. Segers does not disclose or suggest limitation (ii) a second solution containing dipotassium hydrogen phosphate (emphasis added) and at least one amino acid selected from the group consisting of L-leucine, L-isoleucine, L-valine, L-lysine hydrochloride, L-threonine, L- tryptophan, L-methionine, L-phenylalanine, L-cysteine, L-tyrosine, L-arginine, L-histidine, L-alanine, L-proline, L-serine, glycine, L-aspartic acid and L-glutamic acid in a second chamber as recited in claim 24. Applicant also argues that Segers neither discloses nor suggests the first solution and the second solution having a potassium ion concentration of about 13 to 35 mEq/L (emphasis added) of limitation (iii) of claim 24. In addition, there is neither motivation nor clue for those skilled in the art to adopt the claimed potassium ion concentration of about 13 to 35 mEq/L before mixing the first solution and the second solution. Further, the claimed potassium concentration range of about 13 to 35 mEq/L is far from the range of 0.0 to about 3.0 mmol/L of Segers and potassium is contained as not an essential component but an optional component. Therefore, those skilled in the art would not have arrived at the invention of claim 24 from Segers.

The above assertions are not found persuasive because while the rejections are based on the combined teachings of th Segers et al., Veech, Nakamura et al., Panter-Brick, and Kido et al., applicant is resorting to attacking the references individually in the instant case Segers only. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). As described in the previous Office action although Segers et al., teach the incorporation of potassium in concentration 0.0 to about 3.0 (mmol/L) in the final mixture, which the examiner believes would be expected to behave similarly as in the instantly recited concentration ranges, Segers et al., do not explicitly teach the concentrations of potassium ion in each chamber from about 13 to 35 mEq/L. Segers et al., is silent with regard to the concentration of the potassium ion in each chamber. These deficiencies are cured by the teachings of Veech.
Veech teaches electrolyte solutions are provided which are useful in electrolyte and fluid therapy, parenteral nutrition, and dialysis (see abstract). Veech teaches electrolyte solution compositions for example in column 35 table III on the example with broader range contains 0 to about 90 millimoles/L. Veech teaches the electrolyte solutions of such Table III, as indicated above, are useful in such applications as intravenous administration for replacement of electrolytes and fluids, for parenteral nutrition, for dialysis, and the like (column 35, lines 62-65).

Segers et al., is silent whether the material is plastic or not as recited in instant claim 30. Segers et al., even if they teach the incorporation of amino acids, Segers et al., are silent on specific list of amino acids. These deficiencies are cured by the teaching of Nakamura et al. Nakamura et al teach a preparation contained in a plastic bag with two chambers which are separated by a seal which can be opened in order to mix the contents of the two chambers. One chamber contains a solution of amino acids and the other contains albumin (column 4, lines 18-36). Branched amino acids in the present invention include amino acids having a branched alkyl group in the side chain thereof, that is, L-valine, L-leucine or L-isoleucine, and any of these amino acids can be used. Other amino acids are aliphatic amino acids such as straight-chain amino acids (glycine, L-alanine), hydroxy amino acids (L-serine, L-threonine), acidic amino acids (L-aspartic acid, L-glutamic acid), amido-type amino acids (L-asparagine, L-glutamine), basic amino acids (L-lysine, L-hydroxy lysine, L-arginine), and sulfur-containing amino acids (L-cystein, L-cystine, L-methione) (column 2, lines 26-40).

Although Segers et al., teach the upper chamber 44 contains calcium chloride and magnesium chloride, whereas the lower container 46 contains bicarbonate (column 7, lines 34-37). In a preferred embodiment, the upper chamber 44 can further include sodium chloride, potassium chloride, dextrose and dextrose polymers (column 7, lines 37-39). Likewise, the lower chamber 46 can further include sodium chloride, potassium chloride, amino acids, peptides and glycerol (column 7, lines 39-41), Segers et al., do not teach the incorporation of dipotassium hydrogen phosphate in both chambers. Segers et al., do not teach also the incorporation of sodium lactate, calcium gluconate, magnesium sulfate, and zinc sulfate. These deficiencies are cured by the teachings of Kido et al., and Panter-Brick.
Kido et al., teach an infusion preparation set (a container filled with infusion liquids) useful for preparation of an infusion liquid containing sugars, amino acids, electrolytes, a fat emulsion and vitamins (see abstract). Kido et al., teach that examples of the amino acids include various amino acids (essential and non-essential amino acids) which have been used in conventional amino acid infusion preparations for supplying the living body with nutrients, such as L-isoleucine, L-leucine, L-valine, L-lysine, L-methionine, L-phenylalanine, L-threonine, L-tryptophan, L-arginine, L-histidine, glycine, L-alanine, L-proline, L-aspartic acid, L-serine, L-tyrosine, L-glutamic acid, L-cysteine and the like (column 5, lines 48-67). Various types of water soluble salts which have been used in the prior art infusion preparations can be used as electrolytes, including chlorides, sulfates, acetates, gluconates, lactates and the like, water soluble salts of various inorganic components such as sodium, potassium, calcium, magnesium, zinc, iron, copper, manganese, iodine, phosphorus and the like, which are considered to be essential for the maintenance of biological functions and electrolyte balance in the body fluid (column 6, lines 1-10). The preferred electrolyte components include the following compounds: Sodium: sodium chloride, sodium lactate, sodium acetate, sodium sulfate and sodium glycerophosphate; Calcium: calcium gluconate, calcium chloride, calcium glycerophosphate, calcium lactate, calcium pantothenate and calcium acetate; Magnesium: magnesium sulfate, magnesium chloride, magnesium glycerophosphate, magnesium acetate and magnesium lactate; Zinc: zinc sulfate, zinc chloride, zinc gluconate, zinc lactate and zinc acetate (column 6, lines 23-44).
Panter-Brick teaches intravenous nutrition of metabolic mineral composition containing calcium lactate, dipotassium hydrogen phosphate, disodium hydrogen phosphate, magnesium sulfate, calcium chloride, zinc sulfate etc. (page 47 Table 5).

b). Veech

Applicant argues Veech neither discloses nor suggests the first solution containing the specific combination of dipotassium hydrogen phosphate and glucose and the like and the second solution containing the specific combination of dipotassium hydrogen phosphate and amino acid and the like as recited in limitations (i) and (ii) of claim 24. Further, Veech neither discloses nor suggests that the first solution and the second solution each have a potassium ion concentration of about 13 to 35 mEq/L of limitation (iii) of Claim 24. In Veech, potassium ion concentration of 0 to about 90 mEq/L is not a concentration in each chamber but a concentration at the time of administration. Thus, there is neither motivation nor clue for those skilled in the art to adopt the claimed potassium ion concentration of about 13 to 35 mEq/L before mixing the first solution and the second solution. Further, potassium ion is contained as not an essential component but an optional component in Veech's solution. Therefore, those skilled in the art would not have arrived at the invention of claim 24 from Veech.

The above assertions are not found persuasive because while the rejections are based on the combined teachings of th Segers et al., Veech, Nakamura et al., Panter-Brick, and Kido et al., applicant is resorting to attacking the references individually in the instant case Veech only. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). For Veech to be a proper combinable reference with Segers Veech does not necessarily have to teach combination of dipotassium hydrogen phosphate and glucose and the like and the second solution containing the specific combination of dipotassium hydrogen phosphate and amino acid and the like as recited in limitations (i) and (ii) of claim 24 since those limitations as set forth above are addressed by the teachings of Kido et al., and Panter-Brick. Furthermore, on the contrary Veech teaches electrolyte solutions are provided which are useful in electrolyte and fluid therapy, parenteral nutrition, and dialysis (see abstract). Veech teaches electrolyte solution compositions for example in column 35 table III on the example with broader range contains 0 to about 90 millimoles/L. Veech teaches the electrolyte solutions of such Table III, as indicated above, are useful in such applications as intravenous administration for replacement of electrolytes and fluids, for parenteral nutrition, for dialysis, and the like (column 35, lines 62-65).

c) Nakamura

Applicant argues that Nakamura neither discloses nor suggests a potassium ion concentration itself in the first solution and the second solution. That is, Nakamura is silent about limitation (iii) of claim 24, as well as limitations (i) and (ii) as dipotassium hydrogen phosphate is contained in the first solution and the second solution. Further, in Nakamura, there is neither motivation nor clue for those skilled in the art to adopt the claimed potassium ion concentration of about 13 to 35 mEq/L before mixing the first solution and the second solution. Therefore, those skilled in the art would not have arrived at the invention of claim 24 from Nakamura.

The above assertions are not found persuasive because while the rejections are based on the combined teachings of th Segers et al., Veech, Nakamura et al., Panter-Brick, and Kido et al., applicant is resorting to attacking the references individually in the instant case Nakamura only. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). For Nakamura to be a proper combinable reference with Segers Nakamura does not necessarily have to teach a potassium ion concentration itself in the first solution and the second solution and dipotassium hydrogen phosphate contained in the first solution and the second solution since those limitations as set forth above are addressed by the teachings of Veech, Kido et al., and Panter-Brick.

d) Panter-Brick

Applicant argues that Panter-Brick neither discloses nor suggests use of dipotassium hydrogen phosphate and the concentration of potassium ion before mixing the first solution and the second solution. Further, in Panter-Brick, there is neither motivation nor clue for those skilled in the art to adopt the claimed potassium ion concentration of about 13 to 35 mEq/L before mixing the first solution and the second solution.

The above assertions are not found persuasive because while the rejections are based on the combined teachings of th Segers et al., Veech, Nakamura et al., Panter-Brick, and Kido et al., applicant is resorting to attacking the references individually in the instant case Nakamura only. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). For Panter-Brick to be a proper combinable reference with Segers Panter-Brick does not necessarily have to teach a potassium ion concentration itself in the first solution and the second solution since those limitations as set forth above are addressed by the combined teachings of Segers and Veech. Furthermore, contrary to applicant's assertions Panter-Brick teaches intravenous nutrition of metabolic mineral composition containing calcium lactate, dipotassium hydrogen phosphate, disodium hydrogen phosphate, magnesium sulfate, calcium chloride, zinc sulfate etc. (page 47 Table 5).

e). Kido

Applicant argues Kido neither discloses nor suggest use of dipotassium hydrogen phosphate and the concentration of potassium ion before mixing the first solution and the second solution.

The above assertions are not found persuasive because while the rejections are based on the combined teachings of th Segers et al., Veech, Nakamura et al., Panter-Brick, and Kido et al., applicant is resorting to attacking the references individually in the instant case Kido et al., only. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). For Kido et al., to be a proper combinable reference with

Segers, Kido et al., does not necessarily have to teach a potassium ion concentration itself in the first solution and the second solution and dipotassium hydrogen phosphate since those limitations as set forth above are addressed by the combined teachings of Veech and Panter-Brick.

Unexpected effects of the invention of claim 24:
Applicant argues that in the aseptic combination preparation of claim 24, the potassium ion concentration of each medical solution to be accommodated in a plurality of chambers is adjusted in a proper range, and there is no risk of causing hyperkalemia, etc. As a result, the preparation of claim 24 can prevent adverse effects due to medical errors if the medicinal solution in only one chamber is administered to a patient by mistake (page 6, lines 6 to 15 of the specification).
The purpose and effects disclosed in Segers, Veech, Nakamura, Panter-Brick and Kido are quite different from the effect of eliminating adverse effects caused by a medical mistake.

These assertions are not found persuasive because applicant's alleged preparation of ingerdients with proper concentrations is a conventionally expected routine procedure performed by one of ordinary skill in the art. There is nothing which is unexpected about preparing a given concentration of an ingredient such as potassium since the required amounts of potassium ion on the daily basis by the body and the normal potassium ion concentration under physiological conditions by the body are conventionally known by one of ordinary skill in the art. So does the possible errors that occur in concentrations from mixing and preparations of solution mixtures. Any differences between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected. In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The evidence relied upon should establish "that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance." Ex parte Gelles, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992) (Mere conclusions in appellants' brief that the claimed polymer had an unexpectedly increased impact strength "are not entitled to the weight of conclusions accompanying the evidence, either in the specification or in a declaration."); Ex parte C, 27 USPQ2d 1492 (Bd. Pat. App. & Inter. 1992) (Applicant alleged unexpected results with regard to the claimed soybean plant, however there was no basis for judging the practical significance of data with regard to maturity date, flowering date, flower color, or height of the plant.). See also In re Nolan, 553 F.2d 1261, 1267, 193 USPQ 641, 645 (CCPA 1977) and In re Eli Lilly, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) as discussed in MPEP §716.02(c).

Claims 31 and 37 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Segers et al. (US Patent 5383324), Nakamura et al., (US Patent 6867193, published on March 15, 2005), Kido et al., (US Patent No. 6129925, published on October 10, 2000), and Stone et al. (US Patent 4489097, published on December 18, 1994), for the reasons of record and the reasons set forth herein.

Limitation of claim 31:
Response to arguments:
Applicant set forth the same arguments set forth above Segers, Nakamura, and Kido.
The examiner incorporates the rebuttal arguments set forth above regarding Segers, Nakamura, and Kido by reference herein by reference as well as they are equally applicable in this section.

d) Stone:
Applicant argues that Stone neither discloses nor suggests limitations (iv) and (v) of claim 31.
In addition, Stone neither discloses nor suggests an osmotic pressure ratio itself. That is, Stone neither discloses nor suggests that the first solution and the second solution each have an osmotic pressure ratio of about 1 relative to physiological saline (emphasis added) of limitation (vi) of claim 31. In Stone, there is neither motivation nor clue for those skilled in the art to adopt the claimed osmotic pressure ratio of about 1 relative to physiological saline before mixing the first solution and the second solution.

The above assertions are not found persuasive because while the rejections are based on the combined teachings of th Segers et al., Nakamura et al., Kido et al., and Stone et al., applicant is resorting to attacking the references individually in the instant case Stone et al., only. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). For Stone et al., to be a proper combinable reference with Segers, Stone does not necessarily have to teach limitations (iv) and (v) of claim 31 or that the first solution and the second solution each have an osmotic pressure ratio of about 1 relative to physiological saline since these limitations are addressed by the teachings of Nakamura and Kido. Stone is incorporated to render obvious the incorporation of potassium dihydrogen phosphate.

Unexpected effects of the invention of claim 31:

Applicant argues that in the aseptic combination preparation of claim 31, the potassium ion concentration of each medical solution to be accommodated in a plurality of chambers is adjusted in a proper range, and there is no risk of causing hyperkalemia, etc. As a result, the preparation of claim 24 can prevent adverse effects due to medical errors if the medicinal solution in only one chamber is administered to a patient by mistake (page 6, lines 6 to 15 of the specification).
The purpose and effects disclosed in Segers, Nakamura, Kido, and Stone are quite different from the effect of eliminating adverse effects caused by a medical mistake.

These assertions are not found persuasive because applicant's alleged preparation of ingerdients with proper concentrations is a conventionally expected routine procedure performed by one of ordinary skill in the art. There is nothing which is unexpected about

preparing a given concentration of an ingredient such as potassium since the required amounts of potassium ion on the daily basis by the body and the normal potassium ion concentration under physiological conditions by the body are conventionally known by one of ordinary skill in the art. So does the possible errors that occur in concentrations from mixing and preparations of solution mixtures. Any differences between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected. In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The evidence relied upon should establish "that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance." Ex parte Gelles, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992) (Mere conclusions in appellants' brief that the claimed polymer had an unexpectedly increased impact strength "are not entitled to the weight of conclusions accompanying the evidence, either in the specification or in a declaration."); Ex parte C, 27 USPQ2d 1492 (Bd. Pat. App. & Inter. 1992) (Applicant alleged unexpected results with regard to the claimed soybean plant, however there was no basis for judging the practical significance of data with regard to maturity date, flowering date, flower color, or height of the plant.). See also In re Nolan, 553 F.2d 1261, 1267, 193 USPQ 641, 645 (CCPA 1977) and In re Eli Lilly, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) as discussed in MPEP §716.02(c).